MOLECULAR LIBRARIES SCREENING INSTRUMENTATION

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EXPIRATION DATE: October 23, 2004

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:
National Institutes of Health (NIH)
(http://www.nih.gov)

This Request for Application (RFA) is developed as an NIH Roadmap initiative (http://nihroadmap.nih.gov). All NIH institutes and centers (ICs) participate in Roadmap initiatives. This RFA will be administered by the National Human Genome Research Institute (NHGRI)
(http://www.genome.gov) on behalf of NIH.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 93.172

LETTER OF INTENT RECEIPT DATE: September 22, 2004
APPLICATION RECEIPT DATE: October 22, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS RFA

The National Institutes of Health invites research applications to develop innovative instrumentation to accelerate the pace and maximize the efficiency of molecular library high throughput screening. This RFA is one component of the Molecular Libraries and Imaging Initiative of the NIH Roadmap. Investigators are encouraged to collaborate, as appropriate, with investigators working on assay development and on establishment of screening centers for the Molecular Libraries and Imaging Initiative.

Applications in response to this RFA should propose design-directed, discovery-driven, or hypothesis-driven research on high throughput screening instrumentation. It is expected that research proposals will include specific aims with quantitative measures of anticipated achievements, and well-defined milestones that chart key steps toward the goal of innovative and substantial advances in instrumentation.

The NIH Roadmap initiatives encourage multidisciplinary approaches. Investigators who may be new to NIH and biomedical research, from fields such as physics, chemistry, or engineering, are encouraged to participate in this program.

RESEARCH OBJECTIVES

The NIH Roadmap is a series of new initiatives designed to identify major opportunities and gaps in biomedical research that no single NIH institute could tackle alone but which the agency as a whole can pursue to stimulate the progress of biomedical research and to catalyze changes that will serve to transform new scientific knowledge into tangible benefits for public health (http://nihroadmap.nih.gov/).

The Molecular Libraries and Imaging Initiative (MLII) (http://nihroadmap.nih.gov/molecularlibraries/index.asp) is one of the components comprising the Roadmap theme of 'New Pathways to Discovery'. Its goal is to build a better "toolbox" to advance our understanding of the interconnected networks of molecules that comprise cells and tissues, their interactions, regulation, and the combination of molecular events that lead to disease. One objective of the MLII is to develop a publicly available database of biological activities for small organic molecules and to provide access to these molecules to the scientific community. This initiative is expected to promote the use of chemical probes to study cellular pathways in greater depth and to provide new options for investigating the functions of major components of the cell in health and disease. Crucial to the objectives of the MLII is also the development of novel assays and instrumentation for assessing activities of small molecules and probes and for facilitating their application to studies of biology and pathophysiology. The MLII will provide unprecedented access for the academic community to such resources and knowledge, and ultimately will enable and catalyze the identification of novel targets for therapeutic intervention.

This announcement is focused on development of innovative instrumentation for high throughput screening of synthetic chemical and natural product libraries such as the ones

that will be registered and housed in the NIH-sponsored molecular libraries screening centers.

High throughput molecular screening (HTS) is the automated, rapid testing of thousands of distinct small molecules or probes in cellular models of biological mechanisms or disease, or in biochemical or pharmacological assays. Active compounds identified through HTS can provide powerful research tools to elucidate biological processes through chemical genetic approaches, or can form the basis of therapeutics or imaging agent development programs. HTS has experienced revolutionary changes in technology since the advent of molecular biology and combinatorial chemistry, and the incorporation of modern information management systems. Current HTS instrumentation allows screening of hundreds of thousands of compounds in a single day at a rate orders of magnitude greater than was possible a decade ago. However, there are still bottlenecks which currently limit HTS capacity, such as (a) compound collection maintenance, tracking, and disbursement, and (b) rapidity, accuracy, and content of assay instrumentation.

This RFA seeks to develop HTS instrumentation that is not only faster and more efficient than currently available systems, but also substantially more sensitive with high levels of specificity, reproducibility, and accuracy. Other important criteria include greater screening capacity, flexibility, and multiplexing capabilities. Examples of potential research areas that are responsive to this RFA include, but are not limited to:

o novel high throughput screening system integrationo innovative methods for highly parallel ligand/target binding detection
o innovative microfluidics and lab-on-chip technologies
o improved cell-based “high-content” assay formats to acquire many outputs in parallel
o innovative methods for data acquisition and management

All applications are expected to describe clearly advantages in efficiency and/or scale versus current technologies. A description of the practical application of instrumentation derived from the proposed research must also be included.

MECHANISM OF SUPPORT

This RFA will use the NIH R01 award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. NIH encourages multidisciplinary research. It is expected that the PI will bring together the necessary physical, engineering and biological expertise and resources to successfully achieve the goals of the RFA. This RFA is a one-time solicitation. Future unsolicited, competing-continuation applications based on this project will compete with all investigator-initiated applications and will be reviewed according to the customary peer review procedures. The earliest expected award date is June, 2005. Applications that are not funded in the competition described in this RFA may be resubmitted as NEW investigator-initiated applications using the standard receipt dates for NEW applications described in the instructions to the PHS 398 application form.

The initial support for an R01 award in response to this RFA may be up to four years.

This RFA uses just-in-time concepts. It also uses the modular budgeting as well as the non-modular budgeting formats (see http://grants.nih.gov/grants/funding/modular/modular.htm).
Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular budget format. Otherwise follow the instructions for non-modular budget research grant applications. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm.

FUNDS AVAILABLE

The NIH intends to commit approximately $4M to fund new competitive grants in response to this RFA. An applicant may request a project period of up to four years. The number of awards and level of support will depend on the number of applications of high scientific merit that are received. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NIH provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

o Domestic for-profit or non-profit organizations
o Public or private institutions, such as universities, colleges, hospitals, and laboratories
o Units of State and local governments
o Eligible agencies of the Federal government

Foreign institutions may not apply; however, participating collaborators can be located at foreign institutions.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

o Milestones that chart key steps towards the goal of innovative and substantial advances in high throughput molecular screening instrumentation
o 25% minimum effort level by the PI
o Investigators are encouraged to collaborate, as appropriate, with investigators in other components of the Molecular Libraries and Imaging Initiative, such as those involved in assay development
(RFA RM-04-012) and in establishment of screening centers (RFA RM-04-017).
These collaborations need not be formalized at the time of the grant application, but funds should be budgeted for this effort. Public and private partnership is also encouraged.

All applications that list direct costs of $500,000 or more per year must also have a plan to address intellectual property and accessibility of research resources, as described below.

Intellectual Property Rights and Accessibility of Research Resources NIH is interested in ensuring that the research resources developed through this RFA become readily available to the research community. Applicants who respond to this RFA must include a plan addressing if, or how, they will exercise their intellectual property rights, should any intellectual property be generated, while making such research resources available to the broader scientific community for research purposes consistent with the goals of the NIH Molecular Libraries and Imaging Initiative. A reasonable time frame for release of materials should be specified in the sharing plan and will be considered during the review. Furthermore, transfers of research resources must be made consistent with the NIH Research Tools Policy (http://ott.od.nih.gov/NewPages/RTguide_final.html) and other NIH sharing policies. In the development of the sharing and intellectual property plans, applicants should confer with their own institution's office(s) responsible for handling technology transfer related matters and/or their sponsored research office. If applicants or their representatives require additional guidance in preparing these plans, they are encouraged to make further inquiries to the appropriate contacts listed below for such matters.

The scientific review group will evaluate the adequacy of the proposed plan for handling intellectual property rights. Comments on the plan and any concerns will be presented in an administrative note in the Summary Statement. These comments will not affect the priority score of the application. NIH program staff, in determining whether the application shall be awarded, will consider the adequacy of the proposed plan. The plan as approved, after negotiation with the applicant when necessary, will be part of the terms and conditions of the award. Evaluation of non-competing continuation applications will include assessment of the awardee's adherence to the proposed plan, and will be a criterion for continued funding of the award. Applicants also are reminded that the grantee institution is required to disclose each subject invention to NIH within two months after the inventor discloses it in writing to grantee institutional personnel responsible for patent matters. The awarding Institute reserves the right to monitor

awardee activity in this area to ascertain if patents or patent applications are adversely affecting the goals of this RFA. Principles and guidelines for recipients of NIH research awards on obtaining and disseminating biomedical research resources can be found at http://ott.od.nih.gov/NewPages/RTguide_final.html. This document also defines terms, parties, responsibilities, prescribes the order of disposition of rights, prescribes a chronology of reporting requirements, and delineates the basis for and extent of government actions to retain rights. Patent rights clauses may be found at 37 CFR Part 401.14 and are accessible from the Interagency Edison web page, http://www.iedison.gov.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Bradley A. Ozenberger, Ph.D.
Division of Extramural Research
National Human Genome Research Institute
National Institutes of Health, DHHS
Suite 4076 - MSC 9305
5635 Fishers Lane
Bethesda, MD 20892-9305
(express/courier services should be directed to Rockville, MD 20852)
Telephone: (301) 496-7531
FAX: (301) 480-2770
Email: bozenberger@mail.nih.gov

Fei Wang, Ph.D.
Division of Discovery Science & Technology
National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health, DHHS
6707 Democracy Boulevard, Suite 200
Bethesda, MD 20892-5477 (20817 for express/courier services)
Telephone: (301)451-4778
Fax: (301)480-4973
Email: wangf@mail.nih.gov

o Direct your questions about peer review issues to:

David T. George, Ph.D.
Office of Scientific Review
National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health, DHHS

6707 Democracy Boulevard, Suite 920, MSC5469
Bethesda, MD 20892-5469 (20817 for express/courier services)
Telephone: (301) 496-8633
Fax: (301) 480-0675
Email: georged1@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Cheryl Chick
Grants Administration Branch
National Human Genome Research Institute
National Institutes of Health, DHHS
Suite 4076 - MSC 9306
5635 Fishers Lane
Bethesda, MD 20892-9306
Telephone: (301) 435-7858
FAX: (301) 402-1951
Email: ChickC@mail.nih.gov

LETTER OF INTENT

Prospective applicants are strongly advised to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Dr. Bradley A. Ozenberger
Division of Extramural Research
National Human Genome Research Institute
National Institutes of Health, DHHS
Suite 4076 - MSC 9305
5635 Fishers Lane
Bethesda, MD 20892-9305
Telephone: (301) 496-7531
FAX: (301) 480-2770

Email: bozenberger@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at http://www.dunandbradstreet.com/. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo,
Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATION PREPARATION INSTRUCTIONS: Follow the PHS 398 instructions for "Preparing Your Application" with the following modifications and additions:

1. Page limitations for applications in response to this RFA have been increased to a maximum of 30 pages from the usual 25-page limit for sections A-D of the "Research Plan". Applicants are encouraged to be concise and use fewer pages.

2. A program plan should list major tasks with a timeline of quantitative milestones for the entire project period. This information should be included in the Research, Design, and Methods section of the application.

3. Budget Items: The PI is expected to devote a minimum of 25% effort to the proposed research. Information documenting and justifying the level of effort on the proposed research activities for all personnel should be included in the application.

4. Applications must include a plan for making available to the research community any technologies developed or enhanced by work conducted as part of this RFA. Investigators using PHS funds are required to make unique research resources readily available for research purposes to qualified individuals within the scientific community when the results have been published. The intent of this policy is not to discourage, impede, or prohibit the organization that develops the unique research resources or intellectual property from commercializing the products.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (20817 for express/courier services)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

David T. George, Ph.D.
Office of Scientific Review
National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health, DHHS
6707 Democracy Boulevard, Suite 920, MSC5469
Bethesda, MD 20892-5469 (20817 for express/courier services)
Telephone: (301) 496-8633
Fax: (301) 480-0675
Email: georged1@mail.nih.gov

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is, the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the sponsoring ICs. Incomplete applications and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to this RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIBIB in accordance with the review criteria stated below. As part of the initial merit review, all

applications will:

o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority scoreo Receive a written critique
o Receive a second level review by the NHGRI National Advisory Council or Board.

REVIEW CRITERIA

The goal of this RFA is to develop innovative instrumentation to accelerate the pace and maximize the efficiency of molecular library high throughput screening. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of this goal. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score.

o Significance
o Approach
o Innovation
o Investigators
o Environment

SIGNIFICANCE: If the specific aims of the application are achieved, will they provide significant advances in Molecular Libraries Screening Instrumentation? Is the research likely to have a significant impact on other areas of this field? Will the technological advances have a significant impact on human health?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is a timetable with adequate research milestones proposed? Are appropriate specifications and evaluation procedures provided for assessing technological progress? Is there a plan for coordination with assay development and implementation components of the public screening centers? If partnership with industry or small business is included, does this positively affect the research goals and technology dissemination?

INNOVATION: Does the project employ new approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

INVESTIGATORS: Is the PI capable of coordinating and managing the proposed research? Is there evidence of successful collaboration among the investigation team? Are the investigators appropriately trained in their disciplines and capable of conducting and contributing to the management of the proposed work?

ENVIRONMENT: Does the scientific and technological environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA

MILESTONES: The research proposals in response to this RFA must have specific aims which include quantitative measures of anticipated achievements and well-defined milestones that chart key steps to achieving the specific aims as specified in the application. Are the milestones achievable? Will Molecular Libraries Screening Instrumentation be significantly advanced by achieving the milestones?

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

TECHNOLOGY SHARING AND DISSEMINATION: Applicants must include a plan in their proposal for the sharing and dissemination of developed technology. The reasonableness of the technology sharing and dissemination plan or the rationale for not sharing research findings and technologies will be assessed by the reviewers. However, reviewers will not factor the proposed sharing and dissemination plan into the determination of scientific merit or priority score.

INTELLECTUAL PROPERTY RIGHTS: Applicants must include a plan addressing if, or how, they will exercise their intellectual property rights, should any intellectual property be generated, while making such research resources available to the broader scientific community for research purposes consistent with the goals of the NIH Molecular Libraries and Imaging Initiative. The reasonableness of the intellectual property rights plan will be assessed by the reviewers. However, reviewers will not factor the proposed intellectual property rights plan into the determination of scientific merit or priority score.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: September 22, 2004
Application Receipt Date: October 22, 2004
Peer Review Date: February - March, 2005
Council Review: May, 2005
Earliest Anticipated Start Date: June, 2005

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit (as determined by peer review)
o Availability of funds
o Programmatic priorities

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

SHARING RESEARCH DATA: Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible.
http://grants.nih.gov/grants/policy/data_sharing
Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human

Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.healthypeople.gov/.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284)(cite appropriate authorizations) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92 (cite relevant regulations). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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Department of Health and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892